MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Simvastatin 16 mg/mL Oral Liquid (Suspension, 150 mL)	FIN	F 003 536v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Simvastatin, USP	2.400	g				
Glycerin, USP	7.5	mL				
Medisca Oral Suspend (Suspending Vehicle)	70.0	mL				
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 150.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic *(protect from moisture whenever possible):* *Glycerin*

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error considerations during preparation, it is suggested to measure an additional **5 to 9%** of the required quantities of ingredients.

Special Instruction: Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn.

This procedure requires the use of very small quantities of ingredients. All calculations and preparation techniques must be verified before dispensing the final product.

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SUGGESTED PREPARATION (for 150 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Simvastatin, USP	2.400	g			
Glycerin, USP §	7.5	mL			
Medisca Oral Suspend (Suspending Vehicle)	70.0	mL			
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 150.0	mL			

§ Weigh / measure just prior to use.
* Takes into account increased batch size conversions and density conversions, if required.

Preparatory Instruction	
1.	**Powder-liquid preparation:** A. Triturate the Simvastatin to form a fine, homogeneous powder. B. Levigate the fine, homogeneous powder (Step 1A) with the Glycerin. End result: Homogeneous liquid-like dispersion.
2.	**Medium integration:** A. Incrementally add the homogeneous liquid-like dispersion (Step 1B) to the Oral Suspend (Suspending Vehicle). Specifications: Continuously mix. End result: Homogeneous liquid-like dispersion.
3.	**Filling to volume:** A. Add Oral Syrup (Flavored Vehicle) to the mixture (Step 2A) to fill to the required batch size (150.0 mL *plus* processing error adjustments). Specifications: Continuously mix. End result: Homogeneous liquid-like dispersion.

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4.	**Product transfer:** A. Transfer the final product into the specified dispensing container (see "Packaging requirements"). Note: Continuously mix the final product during the transfer process into the recommended dispensing containers in order to maintain homogeneity.

SUGGESTED PRESENTATION

Estimated Beyond-Use Date	14 days, refrigerated, as per USP.		Packaging Requirements	- Tightly closed dispensing bottle. - To be administered with a metered dose-measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Cap tightly after use.
	2	Keep out of reach of children.	6	**Shake well before use.**
	3	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	7	Keep refrigerated. Do not freeze.
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	8	Do not take with grapefruit juice.
Pharmacist Instructions	Add any auxiliary labels specific to the active to the dispensing container as deemed necessary.			
Patient Instructions	Contact your pharmacist in the event of adverse reactions.			

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REFERENCES

1.	Glycerin. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 4th Edition*. American Pharmaceutical Association; 2003: 257.
2.	Alvarez-Lueje A, et al. *Stability study of Simvastatin under hydrolytic conditions assessed by liquid chromatography* J AOAC Int, 2005, 88 (6): 1631-6.
3.	Simvastatin (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #8539.
4.	USP <795>. *United States Pharmacopeia XXXI / National Formulary 26.* Rockville, MD. US Pharmacopeial Convention, Inc. 2008.
5.	Simvastatin (Monograph). *United States Pharmacopeia XXXI / National Formulary 26.* Rockville, MD. US Pharmacopeial Convention, Inc. 2008.